

DOCKET NO.: PSU-0020 (99-2205 US)
Application No.: 09/821,839
Office Action Dated: April 25, 2003

PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116

REMARKS/ARGUMENTS

The Official Action dated April 25, 2003 and referenced cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

Status of the prosecution:

The April 25, 2003 Official Action is a final rejection. The Action notes entry of Applicant's amendment filed February 3, 2003. Claims 1-8, 12-14, 17, 18, 25 and 26 are pending. Claims 25 and 26 were withdrawn from consideration.

Claim 5 was objected to for recitation of the word "of" between "acid" and "molecule."

Claims 5 and 14 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description. The examiner states that the recitation of "at least 70% identical to a cyclin domain comprising amino acids 361 through 521 of SEQ ID NO:2" does not find support in the specification, and therefore constitutes new matter.

Claims 1-4, 12 and 13 remain rejected under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description.

Claims 1-8, 12-14, 17 and 18 remain rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement.

Certain claims remain rejected, or stand newly rejected, under 35 U.S.C. §112, second paragraph, for alleged indefiniteness on the following grounds:

(1) claim 3, in the recitation of “approximately” and in the recitation of “one or more exons” in conjunction with “that form an open reading frame having a sequence that encodes a polypeptide approximately 578 amino acids in length” (it is allegedly unclear whether each exon separately, or all exons together, would encode a polypeptide 578 amino acids in length);

(2) claim 1, in the recitation of “abnormal.”

(3) claims 8 and 14(a) in the recitations of “sequence of the one or more exons of SEQ ID NO:1” and sequence comprising the exons of SEQ ID NO:1 (it is allegedly unclear whether all of the exons add up to one copy of SEQ ID NO:1 or multiple copies of SEQ ID NO:1);

(4) claim 14 in the recitation of “consisting essentially of” (it is allegedly unclear what would or would not materially affect the basic and novel characteristics of the invention); and

(5) claim 14(b) in the recitation of “at least 80% identical to the exons of SEQ ID NO:1” (it is allegedly unclear whether the claimed sequence is 80% identical to the entire SEQ ID NO:1 or to each of the exons of SEQ ID NO:1).

Claims 1-8, 12-14, 17 and 18 remain rejected under 35 U.S.C. §101 for allegedly being unsupported by either a specific and substantial asserted utility or a well established utility, and under 35 U.S.C. §112, first paragraph, for alleged lack of enablement on the same grounds.

Claim 1 stands rejected under 35 U.S.C. §102(b) as allegedly anticipated by the disclosure of Grant et al., Proc. Natl. Acad. Sci. USA (1998) 95: 15843-15848. According to the examiner, Grant et al. identically discloses the subject matter of claim 1, because the

recitation in claim 1 of “a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of said gene resulting in a phenotype of abnormal homologous chromosome attachment during the meiotic prophase I” is not interpreted as limiting “a sequence of a gene.”

Current amendments to the specification and claims:

Claims 14, 17 and 18 are canceled herein because their subject matter is believe to be covered by the remaining claims as amended. Claims 25 and 26 were previously withdrawn from consideration as drawn to a non-elected invention, and are now canceled. Thus, claims 1-8, 12 and 13 remain pending.

Claims 1-8 are currently amended. Support for the amendments can be found in the specification. No new matter has been added. Applicant asserts that the claims as amended are in condition for allowance, for the reasons set forth below.

All formal requirements are satisfied:

Claim 5 was objected to for recitation of the word “of” between “acid” and “molecule.” The word “of” was removed from that position, so the claim should now meet formal requirements.

The claims as amended meet all requirements under 35 U.S.C. §112, first paragraph:

Claims 5 and 14 were rejected under 35 U.S.C. §112, first paragraph, for lack of adequate written description on the ground that the recitation of “at least 70% identical to a cyclin domain comprising amino acids 361 through 521 of SEQ ID NO:2” does not have support in the specification and therefore constitutes new matter. Contrary to the examiner’s assertion, that limitation, which now appears in claim 1, is supported by the specification.

First, the cyclin domain at positions 361-521 of SEQ ID NO:2 is highlighted in Fig. 1.

Second, original claim 14, which forms a part of the specification as filed, specifically contemplates "a sequence encoding a polypeptide having at least 70% identity to the cyclin domain of SEQ ID NO:2." Thus, the specification as originally filed supports the recitation of "at least 70% identical to a cyclin domain comprising amino acids 361 through 521 of SEQ ID NO:2." Withdrawal of the rejection for new matter is therefore requested.

Claims 1-4, 12 and 13 stand rejected for alleged lack of adequate written description, on the ground that the claims are directed to a nucleic acid that is not adequately described with respect to its structural or functional properties. Applicant traverses this rejection as applied to the presently amended claims. Claim 1 as amended incorporates the limitation previously found in claim 5, which was not subject to the rejection. Therefore, claim 1 as amended is directed to a nucleic acid molecule that is adequately described with respect to both structural and functional properties. Accordingly, withdrawal of the rejection is requested.

Claims 1-8, 12-14 and 17-18 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement on the ground that the functions ascribed to the claimed nucleic acid and encoded protein are speculative and therefore the skilled artisan could not determine without undue experimentation which sequences homologous to SEQ ID NO:1 should be tested for the desired function. Applicant traverses this rejection as applied to the presently amended claims. The claims are directed to nucleic acids having greater than a specified identity to SEQ ID NO:1 or encoding a cyclin domain-containing protein having greater than a specified identity to SEQ ID NO:2, and having a specified function. The specification sets forth empirical evidence that loss of function of the protein *in situ*, by insertional disruption

of the protein coding region, results in several gross (male sterility) and fine (homolog attachment in meiotic prophase 1, among others) phenotypes that are readily discernable to the skilled artisan. Using the teachings of the specification, the person of skill in the relevant art could readily determine if a homolog of SEQ ID NO:1 possessed the recited function, for example, by (1) using the sequences of SEQ ID NO:1 to inhibit expression of the homolog (e.g., through antisense or co-suppression, to name a few techniques known and taught in the specification) and (2) thereafter observing if one or more of the phenotypes is exhibited. The test of enablement is not simply whether experimentation would have been necessary, but whether such experimentation would have been undue. *See In re Angstadt*, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *See In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). In the art of plant physiology, genetics and molecular biology, the experimentation described above is typical, and therefore is not undue. Accordingly, withdrawal of the rejection is requested.

The claims as amended meet all requirements under 35 U.S.C. §112, second paragraph:

Certain claims remain rejected, or stand newly rejected, under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Applicant submits that the current claim amendments address each of the recited grounds for rejection, as follows:

(1) in claim 3, in the recitation of “approximately” no longer appears, and the recitation of “one or more exons” in conjunction with “that form an open reading frame having a sequence that encodes a polypeptide approximately 578 amino acids in length” no longer appears, nor do those recitations appear in any other pending claim;

(2) the recitation of "abnormal" no longer appears in claim 1 or any other pending claim;

(3) in claims 8 and 14(a), the recitations of "sequence of the one or more exons of SEQ ID NO:1" and "sequence comprising the exons of SEQ ID NO:1" no longer appear, and do not appear in any pending claim;

(4) the recitation of "consisting essentially of" in claim 14 no longer appears (the claim is canceled) and does not appear in any other pending claim; and

(5) claim 14(b) in the recitation of "at least 80% identical to the exons of SEQ ID NO:1" no longer appears in claim 14(b) (canceled) or any other pending claim.

In view of the above, Applicant submits that the claims as amended meet all requirements of 35 U.S.C. §112, second paragraph, and requests withdrawal of the rejections.

The claimed subject matter meets the requirements of 35 U.S.C. §101:

Claims 1-8, 12-14 and 17-18 stand rejected under 35 U.S.C. §101 as allegedly lacking a well established utility or a specific and substantial asserted utility, and under 35 U.S.C. §112, first paragraph, on the ground that the skilled artisan would not know how to use the claimed subject matter. Applicant traverses these rejections as applied to the presently amended claims.

The claims are directed to nucleic acids having greater than a specified identity to SEQ ID NO:1 or encoding a cyclin domain-containing protein having greater than a specified identity to SEQ ID NO:2, and having a specified function of maintaining normal pairing of homologous chromosomes during meiotic prophase I. The specification teaches that the encoded polypeptide has a cyclin domain, and has significant homology to other known cyclins. The specification teaches that other known cyclins have been found to be important

for meiosis and mitosis. The specification teaches how to use the nucleic acids of the invention to specifically inhibit or down-regulate production of the encoded polypeptide in a plant. The specification sets forth empirical evidence that loss of function of the protein *in situ*, by insertional disruption of the protein coding region, results in male sterility in a plant. A nucleic acid molecule that can be used to produce a male sterile plant has a specific and substantial utility, regardless of the specific cellular mechanism by which the encoded polypeptide is acting in the plant. This utility is asserted in the specification, e.g., at the paragraph bridging pages 25-26. It is also a well established utility, in that it is a specific, substantial and credible utility that is well known and immediately apparent from the specification's disclosure of the properties of the nucleic acid, its encoded polypeptide, and plants in which expression of the polypeptide has been blocked.

For these reasons, in addition to those cited in Applicant's previous response (Paper No. 13), it is again asserted that the claimed invention has utility within the meaning of 35 U.S.C. §101, and further that one of skill in the art would know how to use the invention, in satisfaction of the requirements of 35 U.S.C. §112, first paragraph. Accordingly, withdrawal of the rejections is again requested.

The claimed subject matter is novel over the cited prior art:

Claim 1 stands rejected under 35 U.S.C. §102(b) as allegedly anticipated by Grant et al. Proc. Natl. Acad. Sci. USA (1998) 95: 15843-15848. Applicant traverses this rejection as applied to currently amended claim 1. As amended, claim 1 is drawn to an isolated nucleic acid molecule that encodes a cyclin domain-containing polypeptide comprising an amino acid sequence greater than 70% identical to amino acids 361 through 521 of SEQ ID NO:2, wherein the polypeptide functions in meiotic cells of plants to maintain normal pairing of

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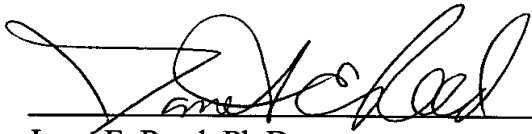
homologous chromosomes during meiotic prophase I. Grant et al. describe a pathogen resistance gene, but nowhere disclose a nucleic acid molecule encoding a polypeptide having the recited function or identity to SEQ ID NO:2. Therefore, Grant et al. cannot be said to identically disclose the subject matter of claim 1. Accordingly Applicant requests withdrawal of this rejection.

Conclusion:

In view of the amendments submitted herewith and the foregoing remarks, the presently-pending claims are believed to be in condition for allowance. Applicants respectfully request early and favorable reconsideration and withdrawal of the objections and rejections set forth in the April 25, 2003 Action, and allowance of this application.

Respectfully submitted:

Date: September 24, 2003



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